

**AFRIN NO DRIP SEVERE CONGESTION- oxymetazoline hydrochloride spray, metered
Delpharm Montreal Inc.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Afrin[®] No Drip

Severe Congestion

Drug Facts

Active ingredient

Oxymetazoline hydrochloride 0.05%

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to:
 - common cold
 - hay fever
 - upper respiratory allergies
- temporarily relieves sinus congestion and pressure
- shrinks swollen nasal membranes so you can breathe more freely

Warnings

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

When using this product

- **do not use more than directed**
- do not use for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen.
- temporary discomfort such as burning, stinging, sneezing or an increase in nasal discharge may occur
- use of this container by more than one person may spread infection

Stop use and ask a doctor if symptoms persist

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 sprays in each nostril not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period.
- children under 6 years of age: ask a doctor.

Shake well before use. Before using the first time, remove the protective cap from the tip and prime metered pump by depressing pump firmly several times. To spray, hold bottle with thumb at base and nozzle between first and second fingers. Without tilting head, insert nozzle into nostril. Fully depress rim with a firm, even stroke and sniff deeply. Wipe nozzle clean after use.

Other information

- store between 20° to 25°C (68° to 77°F)
- retain carton for future reference on full labeling

Inactive ingredients

benzalkonium chloride solution, benzyl alcohol, camphor, edetate disodium, eucalyptol, menthol, microcrystalline cellulose and carboxymethylcellulose sodium, polyethylene glycol, povidone, propylene glycol, purified water, sodium phosphate dibasic, sodium phosphate monobasic

Questions or comments?

Call 1-800-317-2165

Distributed by Bayer HealthCare LLC Whippany, NJ 07981

PRINCIPAL DISPLAY PANEL - 15 mL Bottle Carton

NDC 11523-1350-1

Oxymetazoline HCl Nasal Solution-Nasal Decongestant

Afrin®

NoDrip

Won't drip from nose or down throat

Severe Congestion

PUMP MIST

Fast, Powerful

Congestion

Relief

Colds • Allergies

12

Hour

Relief

Maximum

Strength

plus Menthol

#1 Doctor & Pharmacist

Recommended Brand

1/2 FL OZ (15 mL)



AFRIN NO DRIP SEVERE CONGESTION

oxymetazoline hydrochloride spray, metered

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69213-1350 |
| Route of Administration | NASAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------|------------------|
| OXYMETAZOLINE HYDROCHLORIDE (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY) | OXYMETAZOLINE HYDROCHLORIDE | 0.05 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| EUCALYPTOL (UNII: RV6J6604TK) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74) | |
| SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JH2SW) | |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69213-1350-1 | 1 in 1 CARTON | 08/31/2000 | |
| 1 | | 15 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | | |
| 2 | NDC:69213-1350-2 | 2 in 1 CARTON | 08/31/2000 | |
| 2 | | 20 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | | |
| 3 | NDC:69213-1350-3 | 1 in 1 CARTON | 08/31/2000 | |
| 3 | | 20 mL in 1 BOTTLE, PUMP; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.) | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 08/31/2000 | |

Labeler - Delpharm Montreal Inc. (203565379)

Revised: 7/2020

Delpharm Montreal Inc.